

APPENDIX IX - A

Total number of pages = 485

Data Collection Forms for Subjects Completing the Study

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>158</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S/M/L</u> F M L	Permanent #: <u>1</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>20</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Jamie Busenmeyer

Date:

07/15/03

mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106

Page No.: IV-224

Visit Code	Date	Subject Initials	Subject Screen #: <u>158</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S.M.L</u> f m l	Permanent #: <u>1</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES/	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u>7/24/03</u> <input type="checkbox"/> Post-menopausal, year <u>gh</u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB / 07.15.03

Investigator's Signature: _____

Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>158</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>S/M/L</u> F M L	Permanent #: <u>1</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Erin L. Harris

Date: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>S/M/L</u> F M L	<u>158</u> Permanent #: <u>1</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>163</u>	<u>24</u>	TNTC	<u>116</u>	<u>11</u>
TNTC	<u>143</u>	<u>13</u>	TNTC	<u>149</u>	<u>14</u>
CFU/mL <u>8x10⁷</u> Counted by: <u>AKB</u> / 7.28.03			CFU/mL <u>1.3x10⁷</u> Counted by: <u>AKB</u> / 7.28.03		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>41</u>	<u>6</u>	TNTC	TNTC	<u>55</u>	<u>0</u>
TNTC	TNTC	<u>42</u>	<u>7</u>	TNTC	TNTC	<u>32</u>	<u>3</u>
TNTC				TNTC			
CFU/mL <u>4.2x10⁴</u> Counted by: <u>AKB</u> / 7.28.03				CFU/mL <u>4.4x10⁴</u> Counted by: <u>AKB</u> / 7.28.03			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>91</u>	<u>13</u>	TNTC	<u>232</u>	<u>29</u>	<u>1</u>
TNTC	TNTC	<u>86</u>	<u>12</u>	TNTC	<u>280</u> (*)	<u>22</u>	<u>2</u>
TNTC				TNTC			
CFU/mL <u>8.8x10⁴</u> Counted by: <u>AKB</u> / 7.28.03				CFU/mL <u>2.6x10⁴</u> Counted by: <u>AKB</u> / 7.28.03			

(*) Did not estimate due to the countability of the plate. AKB 7.28.03

Calculations by: JNB / 07.29.03 Raw data reviewed by JNB / 08.01.03Calculations Verified by: TG / 7.29.03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: [Signature]Date: 8/8/03
mm dd yy

Data Collection Form 5A

Subject Initials SML Subject # 1Study No. 03-122085-106Page No. IV-227

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date	
red bumps	7-25-03	8/7/03	N	1	1	1	4	E. L. J. 8-16-03	
Entry Date	Comment/Note: possible due to test organism E-LJ 8-16-03								Initials
7/28/03	red bumps on hands								gh
8/7/03	stated that hand and finger are clear, unwilling to return to lab for follow up check.								gh

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date	
see above for dates	8/5/03	8/8/03							
Entry Date	Comment/Note:								Initials
7-29-02	Four pink papules on hand and finger								E-LJ

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date	
Entry Date	Comment/Note:								Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-228

Visit Code	Date	Subject Initials	Subject Screen #: <u>158</u>	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>S/M/L</u> F M L	Permanent #: <u>1</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/29/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☒ YES☐ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Four pink macules on back of fingers
Onset 7-25-03

Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:

E. L. Jones, M.D.

Date

7/29/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>142</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>J L R</u> F M L	Permanent #: <u>2</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>24</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Buemeyer</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106

Page No.: IV-230

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u>	<u>JILIR</u>	<u>142</u>	
Subject Qualification	mm dd yy	f m l	Permanent #:	03-122085-106
			<u>2</u>	

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
		<input checked="" type="checkbox"/>	8. Is currently lactating ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 107.15.03

Investigator's Signature: *Gayle A. Hall* Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>142</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>J / L / R</u> F M L	Permanent #: <u>2</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ NoIV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ NoBased upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Swann R. HarrisDate: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>J/L/R</u> F M L	<u>142</u> Permanent #: <u>2</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>164</u>	<u>15</u>	TNTC	<u>141</u>	<u>15</u>
TNTC	<u>213</u>	<u>19</u>	TNTC	<u>200</u>	<u>22</u>
CFU/mL <u>1.9 x 10⁷</u> Counted by: <u>JNB 107-28-03</u>			CFU/mL <u>1.7 x 10⁷</u> Counted by: <u>JNB 107-28-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>164</u>	<u>27</u>	TNTC	TNTC	<u>135</u>	<u>23</u>
TNTC	TNTC	<u>129</u>	<u>20</u>	TNTC	TNTC	<u>178</u>	<u>15</u>
TNTC				TNTC			
CFU/mL <u>1.9 x 10⁵</u> Counted by: <u>JNB 107-28-03</u>				CFU/mL <u>1.6 x 10⁵</u> Counted by: <u>JNB 107-28-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>29</u>	<u>5</u>	TNTC	TNTC	<u>33</u>	<u>3</u>
TNTC	TNTC	<u>38</u>	<u>5</u>	TNTC	TNTC	<u>32</u>	<u>7</u>
TNTC				TNTC			
CFU/mL <u>3.4 x 10⁴</u> Counted by: <u>JNB 107-28-03</u>				CFU/mL <u>3.2 x 10⁴</u> Counted by: <u>JNB 107-28-03</u>			

3.2 x 10⁴ 2 JNB 07-29-03

Calculations by: JNB 107-29-03 Raw data reviewed by: ALB 18-1-03

Calculations Verified by: TG 17-29-03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>07/29/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-233

Visit Code	Date 29	Subject Initials	Subject Screen #: 142	Study #
Follow-up Visit	07/15/03 mm dd yy	J / L / R F M L	Permanent #: 2	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/29/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES ☒ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

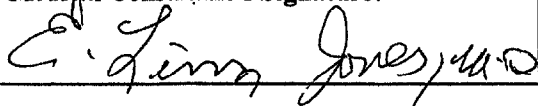
Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES ☒ NO If yes, complete below

Comments:

Medical Consultant's Signature:



Date

7/29/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>106</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M/G/B</u> F M L	Permanent #: <u>3</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>45</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify: <u>see below</u>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	

Is the subject taking any medication? If yes, please specify below:

3SRH/7.15.03

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?		<input checked="" type="checkbox"/>	

Comments: Allopurinol - 300mg 1x/day - Gout/kidney stones
Oracit Soln. - 3 Tbs. /day - Prevention of kidney stones

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Sum K. Horni</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-235

Visit Code	Date	Subject Initials	Subject Screen #: <u>106</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>M/G/B</u> f m l	Permanent #: <u>3</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SKH / 7.15.03

Investigator's Signature: [Signature] Date: 8/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>106</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>M/G/B</u> F M L	Permanent #: <u>3</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☐ Yes ☒ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ NoIV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ NoBased upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Betty M. ConoverDate: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>M/G/B</u> F. M L	<u>106</u> Permanent #: <u>3</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>116</u>	<u>22</u>	TNTC	<u>132</u>	<u>13</u>
TNTC	<u>144</u>	<u>12</u>	TNTC	<u>155</u>	<u>18</u>
CFU/mL <u>1.3×10^7</u> Counted by: <u>JNB</u> <u>107.25.03</u>			CFU/mL <u>1.4×10^7</u> Counted by: <u>JNB</u> <u>107.25.03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	TNTC	TNTC	<u>36</u>	TNTC	TNTC	TNTC	<u>63</u>	TNTC	TNTC	TNTC	<u>46</u>
TNTC	TNTC	TNTC	<u>35</u>	TNTC	TNTC	TNTC		TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>3.6×10^5</u> Counted by: <u>JNB</u> <u>107.25.03</u>				CFU/mL <u>5.4×10^5</u> Counted by: <u>JNB</u> <u>107.25.03</u>							

LEFT HAND				WASH 11				RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	TNTC	TNTC	<u>42</u>	TNTC	TNTC	TNTC	<u>40</u>	TNTC	TNTC	TNTC	<u>40</u>
TNTC	TNTC	TNTC	<u>43</u>	TNTC	TNTC	TNTC	<u>46</u>	TNTC	TNTC	TNTC	
TNTC				TNTC				TNTC			
CFU/mL <u>4.2×10^5</u> Counted by: <u>JNB</u> <u>107.25.03</u>				CFU/mL <u>4.3×10^5</u> Counted by: <u>JNB</u> <u>107.25.03</u>							

Calculations by: TG 17.26.03 Raw data reviewed by: ARB 18.1.03Calculations Verified by: JNB 107.29.03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature:	Date: <u> </u> / <u> </u> / <u> </u> mm dd yy
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Data Collection Form 5A

Subject Initials MGB Subject # 3Study No. 03-122085-106Page No. IV-238

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps	7/25/03	8/4/03	N	1	1	1	4	<i>[Signature]</i> 8/16/03
Entry Date	Comment/Note: Probably due to test organism <i>[Signature]</i> Initials							
7/25/03	red bumps on both hands and wrists <i>[Signature]</i>							
8/4/03	hands clear no medications used <i>[Signature]</i>							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note: Initials							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note: Initials							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-239

Visit Code	Date	Subject Initials	Subject Screen #: <u>106</u>	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>M / G / B</u> F M L	Permanent #: <u>3</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p><u>Five papules on wrists</u></p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. Linn Jones M.D.</u>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			138	
Subject Qualification	07/15/03 mm dd yy	L/E/B F M L	Permanent #: 4	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: 18 Years
--	---------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. Sulfa drugs		✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: depression / anxiety ADD		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? Effexor 150mg 1x day depression / anxiety		✓	

Comments: Other meds: Straterra 25 mg 1x day ADD

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: Jami Busenmeyer	Date: 07/15/03 mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-241

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>138</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L, E, B</u> f m l	Permanent #: <u>4</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β-HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/24/03 JNB</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB, 07.15.03

Investigator's Signature: [Signature]

Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>138</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>L / E / B</u> F M L	Permanent #: <u>4</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Betty M. Conover</u>	Date: <u>07/24/03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>L/E/B</u> F. M L	<u>138</u> Permanent #:	03-122085-106
		<u>4</u>	

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>148</u>	<u>10</u>	TNTC	<u>134</u>	<u>20</u>
TNTC	<u>94</u>	<u>14</u>	TNTC	<u>118</u>	<u>19</u>
CFU/mL <u>1.2x10⁷</u> Counted by: <u>JNB/07-28-03</u>			CFU/mL <u>1.3x10⁷</u> Counted by: <u>JNB/07-28-03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>49</u>	<u>4</u>	TNTC	TNTC	<u>61</u>	<u>4</u>		
TNTC	TNTC	<u>53</u>	<u>6</u>	TNTC	TNTC	<u>50</u>	<u>5</u>		
TNTC				TNTC					
CFU/mL <u>5.1x10⁴</u> Counted by: <u>ARB/7-28-03</u>				CFU/mL <u>5.6x10⁴</u> Counted by: <u>ARB/7-28-03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	<u>120</u>	<u>10</u>	<u>3</u>	TNTC	<u>90</u>	<u>15</u>	<u>3</u>		
TNTC	<u>82</u>	<u>11</u>	<u>1</u>	TNTC	<u>81</u>	<u>12</u>	<u>4</u>		
TNTC				TNTC					
CFU/mL <u>1.0x10⁴</u> Counted by: <u>ARB/7-28-03</u>				CFU/mL <u>8.6x10³</u> Counted by: <u>ARB/7-28-03</u>					

Calculations by: JNB / 07-29-03 Raw data reviewed by SAS / 8-1-03Calculations Verified by: TG / 7-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8</u> / <u>8</u> / <u>03</u> mm dd yy
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Data Collection Form 5A

Subject Initials LEB Subject # 4Study No. 03-122085-106Page No. II-97II-244

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Reaction to Effexor	6/9/03	7/31/03	N	1	1	1	4	E. Lynn Jones 8-16-03
Entry Date	Comment/Note:							Initials
8/6/03	Took 225mg effexor for anxiety 1x day from 6/9/03 to 7/31/03, discontinued use due to neurological problems							gfu

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-2445

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	07/29/03 mm dd yy	L / E / B F M L	138 Permanent #: 4	03-122085-106

③ 4/6/03
JH

Date Subject Entered the Study: 07/15/03 mm dd yy	Follow-Up Visit Date: 07/29/03 mm dd yy
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Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES ☒ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

Has the subject had any health related issues since the treatment procedure?

☒ YES ☐ NO If yes, complete below

Comments: Drug reaction - Effxon.

Medical Consultant's Signature: E. Luis Lopez	Date: 7/29/03 mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>102</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L J B</u> F M L	Permanent #: <u>5</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>65</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Busmeyer</u>	Date: <u>07 / 15 / 03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-247

Visit Code	Date	Subject Initials	Subject Screen #: <u>102</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L J B</u> f m l	Permanent #: <u>5</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1972</u> <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 107-15-03

Investigator's Signature: _____

Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>102</u>	Study #
Test Period	<u>07 / 24 / 03</u> mm dd yy	<u>L / J / B</u> F M L	Permanent #: <u>5</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Guan R. Harris

Date: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>LJB</u> F. M L	<u>102</u> Permanent #: <u>5</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNT	<u>214</u>	<u>35</u>	TNT	<u>216</u>	<u>23</u>
TNT	<u>222</u>	<u>19</u>	TNT	<u>182</u>	<u>15</u>
CFU/mL <u>2.4×10^7</u> Counted by: <u>ARB / 7.28.03</u>			CFU/mL <u>2.0×10^7</u> Counted by: <u>ARB / 7.28.03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
TNT	TNT	<u>79</u>	<u>12</u>	TNT	TNT	<u>179</u>	<u>16</u>		
TNT	TNT	<u>114</u>	<u>6</u>	TNT	TNT	<u>151</u>	<u>26</u>		
TNT				TNT					
CFU/mL <u>9.6×10^4</u> Counted by: <u>ARB / 7.28.03</u>				CFU/mL <u>1.8×10^5</u> Counted by: <u>ARB / 7.28.03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
<u>160</u>	<u>94</u>	<u>6</u>	<u>0</u>	TNT	<u>175</u>	<u>15</u>	<u>3</u>		
<u>161</u>	<u>59</u>	<u>10</u>	<u>0</u>	TNT	<u>107</u>	<u>24</u>	<u>0</u>		
<u>174</u>				TNT					
CFU/mL <u>6.8×10^3</u> Counted by: <u>ARB / 7.28.03</u>				CFU/mL <u>1.4×10^4</u> Counted by: <u>ARB / 7.28.03</u>					

Calculations by: JNB 107.29.03 Raw data reviewed by JNB 108.01.03Calculations Verified by: TR 17.29.03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>B. S. Smiley</u>	Date: <u>8/1/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-250

Visit Code	Date	Subject Initials	Subject Screen #: <u>102</u>	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>L / J / B</u> F M L	Permanent #: <u>5</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: 	Date <u>7/29/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>154</u>	Study #
Subject Qualification	<u>07</u> / <u>15</u> / <u>03</u> mm dd yy	<u>L</u> / <u>M</u> / <u>P</u> F M L	Permanent #: <u>6</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>21</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jamie Basemeyer</u>	Date: <u>07</u> / <u>15</u> / <u>03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV - 252

Visit Code	Date	Subject Initials	Subject Screen #: <u>154</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>L, M, P</u> f m l	Permanent #: <u>6</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/24/03 ghr</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB, 07.15.03

Investigator's Signature: _____

Date: 07/01/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>154</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>L M P</u> F M L	Permanent #: <u>6</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ NoIV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ NoBased upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Betty M. ConoverDate: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>L/M/P</u> F. M L	<u>154</u> Permanent #: <u>6</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>208</u>	<u>24</u>	TNTC	<u>146</u>	<u>16</u>
TNTC	<u>190</u>	<u>16</u>	TNTC	<u>124</u>	<u>20</u>
CFU/mL <u>2.0×10^7</u> Counted by: <u>AMB 17.28.03</u>			CFU/mL <u>1.4×10^7</u> Counted by: <u>AMB 17.28.03</u>		

LEFT HAND				WASH 1				RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	TNTC	<u>108</u>	<u>21</u>	TNTC	TNTC	<u>98</u>	<u>11</u>	TNTC	TNTC	<u>98</u>	<u>11</u>
TNTC	TNTC	<u>148</u>	<u>17</u>	TNTC	TNTC	<u>93</u>	<u>8</u>	TNTC	TNTC	<u>93</u>	<u>8</u>
TNTC				TNTC				TNTC			
CFU/mL <u>1.3×10^5</u> Counted by: <u>AMB 17.28.03</u>				CFU/mL <u>9.6×10^4</u> Counted by: <u>AMB 17.28.03</u>				CFU/mL <u>9.6×10^4</u> Counted by: <u>AMB 17.28.03</u>			

LEFT HAND				WASH 11				RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	TNTC	<u>36</u>	<u>4</u>	TNTC	<u>152</u>	<u>11</u>	<u>1</u>	TNTC	<u>152</u>	<u>11</u>	<u>1</u>
TNTC	TNTC	<u>26</u>	<u>3</u>	TNTC	<u>160</u>	<u>23</u>	<u>3</u>	TNTC	<u>160</u>	<u>23</u>	<u>3</u>
TNTC				TNTC				TNTC			
CFU/mL <u>3.1×10^4</u> Counted by: <u>AMB 17.28.03</u>				CFU/mL <u>1.6×10^4</u> Counted by: <u>AMB 17.28.03</u>				CFU/mL <u>1.6×10^4</u> Counted by: <u>AMB 17.28.03</u>			

Calculations by: JNB 107.29.03 Raw data reviewed by JNB 108.01.03Calculations Verified by: TE 17.29.03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>08/01/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials LMP Subject # 6Study No. 03-122085-106Page No. IV-255

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
<i>Papules</i>	<i>7-25-03</i>	<i>8/7/03</i>	<i>N</i>	<i>1</i>	<i>1</i>	<i>1</i>	<i>4</i>	<i>E. J. J.</i>
Entry Date	Comment/Note:							Initials
<i>7-29-03</i>	<i>Probably due to test organism & 8-16-03</i>							<i>E. J. J.</i>
	<i>Three red papules on backs of</i>							<i>8-16-03</i>
	<i>hand and fingers.</i>							<i>7-29-03</i>
<i>8/7/03</i>	<i>Hands + fingers clear no medications</i>							<i>gn</i>
	<i>used</i>							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relationship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-256

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>L M P</u> F M L	<u>154</u> Permanent #: <u>6</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.) <u>Three red papules on back of hand + finger</u> <u>Onset 7-25-03</u></p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. Lewis Jr., MD</u>	Date <u>7/29/03</u> mm dd yy
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DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>113</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>P/A/D</u> F M L	Permanent #: <u>7</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>58</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>high blood pressure</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>high cholesterol</u>		✓	

Is the subject taking any medication? If yes, please specify below:

HRT ^①

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>gem fibronil 600mg 1x day</u> ^①	✓	✓	
4. Insulin ?	✓		
5. Other ? <u>Welchol 625mg 1x day - cholesterol</u> ^①		✓	
Comments: <u>Evista 60mg 1x day - HRT</u> ^① <u>monopril 10 mg 1x day - blood pressure</u> ^① <u>① added as per subject 7/15/03 gr</u>			

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Busmeyer</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-258

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u> mm dd yy	<u>P A D</u> f m l	<u>113</u> Permanent #: <u>7</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1998</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07-15-03

Investigator's Signature: [Signature] Date: 07/15/03
mm dd yy

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>113</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>P / A / D</u> F M L	Permanent #: <u>7</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 260

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>P/A/D</u> F M L	<u>113</u> Permanent #: <u>7</u>	03-122085-106

BASELINE						
LEFT HAND DILUTIONS				RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶		10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>165</u>	<u>22</u>		TNTC	<u>158</u>	<u>14</u>
TNTC	<u>150</u>	<u>27</u>		TNTC	<u>173</u>	<u>12</u>
CFU/mL <u>2.0 × 10⁷</u> Counted by: <u>Qn / 7.25.03</u>				CFU/mL <u>1.6 × 10⁷</u> Counted by: <u>Qn / 7.25.03</u>		

LEFT HAND				WASH 1	RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>242</u>	<u>67</u>	<u>6</u>		TNTC	TNTC	<u>40</u>	<u>8</u>
TNTC	<u>254</u>	<u>78</u>	<u>11</u>		TNTC	TNTC	<u>48</u>	<u>3</u>
TNTC					TNTC			
CFU/mL <u>4.9 × 10⁴</u> Counted by: <u>Qn / 7.25.03</u>					CFU/mL <u>4.4 × 10⁴</u> Counted by: <u>Qn / 7.25.03</u>			

① did not estimate due to countability of plate
8.6.03 Qn

LEFT HAND				WASH 11	RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>51</u>	<u>6</u>		TNTC	TNTC	<u>50</u>	<u>5</u>
TNTC	TNTC	<u>61</u>	<u>5</u>		TNTC	TNTC	<u>58</u>	<u>12</u>
TNTC					TNTC			
CFU/mL <u>5.6 × 10⁴</u> Counted by: <u>Qn / 7.25.03</u>					CFU/mL <u>5.4 × 10⁴</u> Counted by: <u>Qn / 7.25.03</u>			

Calculations by: TG / 7.26.03 Raw data reviewed by: QRB / 8.1.03

Calculations Verified by: JNB / 07.29.03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature:	Date: <u> </u> / <u> </u> / <u> </u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-261

Visit Code	Date	Subject Initials	Subject Screen #: <u>113</u>	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>P/A/D</u> F M L	Permanent #: <u>7</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/28/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES☒ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

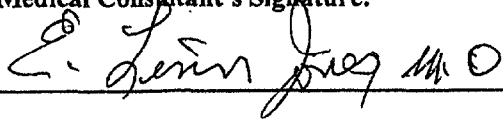
Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:



Date

7/28/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>123</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A, L, B</u> F M L	Permanent #: <u>8</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>31</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify: <u>depression</u>		<input checked="" type="checkbox"/>	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ? <u>Zoloft 50mg 1xday (depression)</u>		<input checked="" type="checkbox"/>	

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Stacy E Bachuding</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-263

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A, L, B</u> f m l	<u>123</u> Permanent #: <u>8</u>	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one				Subject:
YES	NO	N/A		
	<input checked="" type="checkbox"/>			1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>			2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>			3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>			4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>			6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male		7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u>7/23/03</u> <input type="checkbox"/> Post-menopausal, year <u>7/23/03</u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive
	<input checked="" type="checkbox"/>			8. Is currently lactating ?
	<input checked="" type="checkbox"/>			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>			10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SOB, 7/15/03

Investigator's Signature: E K Gaulty

Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>123</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>A/L/B</u> F M L	Permanent #: <u>8</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>James L. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>A / L / B</u> F. M L	<u>123</u> Permanent #: <u>8</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>143</u>	<u>18</u>	TNTC	<u>136</u>	<u>18</u>
TNTC	<u>199</u>	<u>19</u>	TNTC	<u>150</u>	<u>13</u>
CFU/mL <u>1.7×10^7</u> Counted by: <u>JNB 107.25.03</u>			CFU/mL <u>1.4×10^7</u> Counted by: <u>JNB 107.25.03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
TNTC	TNTC	TNTC	<u>32</u>	TNTC	TNTC	<u>81</u>	<u>15</u>		
TNTC	TNTC	TNTC	<u>51</u>	TNTC	TNTC	<u>96</u>	<u>10</u>		
TNTC				TNTC					
CFU/mL <u>4.2×10^5</u> Counted by: <u>JNB 107.25.03</u>				CFU/mL <u>8.8×10^4</u> Counted by: <u>JNB 107.25.03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
TNTC	TNTC	<u>234</u>	<u>24</u>	TNTC	TNTC	<u>152</u>	<u>29</u>		
TNTC	TNTC	⑩ <u>278</u>	<u>49</u>	TNTC	TNTC	<u>197</u>	<u>26</u>		
TNTC				TNTC					
CFU/mL <u>3.1×10^5</u> Counted by: <u>gfh 17.25.03</u>				CFU/mL <u>2.2×10^5</u> Counted by: <u>gfh 17.25.03</u>					

⑩ plates counted due to countability of plate 7.25.03 gfh

Calculations by: Tk 17.26.03 Raw data reviewed by: Qlb 18.1.03Calculations Verified by: JNB 107.29.03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8</u> <u>18</u> <u>103</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-266

Visit Code	Date	Subject Initials	Subject Screen #: <u>123</u>	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>A / L / B</u> F M L	Permanent #: <u>8</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: 	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>150</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A.P.D</u> F M L	Permanent #: <u>9</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>46</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:			

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Jami Busmeyer

Date:

07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106

Page No.: IV-268

Visit Code	Date	Subject Initials	Subject Screen #: <u>150</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>A.P.D</u> f m l	Permanent #: <u>9</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u>7</u> <input type="checkbox"/> Post-menopausal, year <u>7/24/03 ga</u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:

☒ **Qualified** ☐ **Not Qualified**

for participation in this study.

Reasons for disqualification:

Interviewer's Initials/Date: JNB 07/15/03

Investigator's Signature: [Signature]

Date: 07/15/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>150</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>A / P / D</u> F M L	Permanent #: <u>9</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Sam R. Harris

Date: 07 / 24 / 03
mm dd yy

Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 270

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>A/P/D</u> F M L	<u>150</u> Permanent #: <u>9</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>226</u>	<u>9</u>	TNTC	<u>224</u>	<u>20</u>
TNTC	<u>190</u>	<u>18</u>	TNTC	<u>138</u>	<u>12</u>
CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>AS</u> / 7-28-03			CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>AS</u> / 7-28-03		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>181</u>	<u>26</u>	TNTC	TNTC	<u>224</u>	<u>25</u>		
TNTC	TNTC	<u>178</u>	<u>21</u>	TNTC	TNTC	<u>213</u>	<u>22</u>		
TNTC				TNTC					
CFU/mL <u>2.1 x 10⁵</u> Counted by: <u>AS</u> / 7-28-03				CFU/mL <u>2.3 x 10⁵</u> Counted by: <u>AS</u> / 7-28-03					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>38</u>	<u>5</u>	TNTC	TNTC	<u>31</u>	<u>1</u>		
TNTC	TNTC	<u>45</u>	<u>4</u>	TNTC	TNTC	<u>34</u>	<u>2</u>		
TNTC				TNTC					
CFU/mL <u>4.2 x 10⁴</u> Counted by: <u>AS</u> / 7-28-03				CFU/mL <u>3.2 x 10⁴</u> Counted by: <u>AS</u> / 7-28-03					

Calculations by: JNB / 07-29-03 Raw data reviewed by: ARB / 8-1-03Calculations Verified by: TC / 7-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/8/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-271

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>A P D</u> F M L	<u>150</u> Permanent #: <u>9</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. L. Jones, M.D.</u>	Date <u>7/29/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 115	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>R/L/M</u> F M L	Permanent #: 10	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>62</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease?	/		
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify: <u>back, hip</u>		/	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ?	/		
4. Insulin ?	/		
5. Other ? <u>Vicodin 5 mg 4xday when needed</u>		/	

Comments: 11 mg added as per subject 7/15/03 gsnBased on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Stacey E Bocheiding</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-273

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>R/L/M</u> f m l	<u>115</u> Permanent #: <u>10</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB, 7/15/03

Investigator's Signature: [Signature]

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>115</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>R / L / M</u> F M L	Permanent #: <u>10</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☐ Yes ☒ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ NoIV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ NoBased upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Betty M. Conover</u>	Date: <u>07/23/03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 275

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>R/L/M</u> F. M L	<u>115</u> Permanent #: <u>10</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>156</u>	<u>17</u>	TNTC	<u>146</u>	<u>20</u>
TNTC	<u>142</u>	<u>10</u>	TNTC	<u>138</u>	<u>24</u>
CFU/mL <u>1.5 × 10⁷</u> Counted by: <u>JNB / 07-25-03</u>			CFU/mL <u>1.4 × 10⁷</u> Counted by: <u>JNB / 07-25-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	TNTC	<u>88</u>	TNTC	TNTC	TNTC	<u>51</u>
TNTC	TNTC	TNTC	<u>97</u>	TNTC	TNTC	TNTC	<u>53</u>
TNTC				TNTC			
CFU/mL <u>9.2 × 10⁵</u> Counted by: <u>JNB / 07-25-03</u>				CFU/mL <u>5.2 × 10⁵</u> Counted by: <u>JNB / 07-25-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>155</u>	<u>19</u>	TNTC	TNTC	<u>172</u>	<u>29</u>
TNTC	TNTC	<u>201</u>	<u>24</u>	TNTC	TNTC	<u>197</u>	<u>30</u>
TNTC				TNTC			
CFU/mL <u>1.8 × 10⁵</u> Counted by: <u>JNB / 07-25-03</u>				CFU/mL <u>2.4 × 10⁵</u> Counted by: <u>JNB / 07-25-03</u>			

Calculations by: TC / 7-26-03 Raw data reviewed by ALB / 8-1-03Calculations Verified by: JNB / 07-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-276

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>R / L / M</u> F M L	<u>115</u> Permanent #: <u>10</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. Linton Jones, MD</u>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			108	
Subject Qualification	07/15/03 mm dd yy	S/L/B F M L	Permanent #:	03-122085-106
			11	

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>63</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify. <u>seasonal</u>	✓	✓	
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? <u>high blood pressure</u>		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>hypothyroidism</u>		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? <u>Atapro 250mg 1x day</u>		✓	
4. Insulin ?	✓		
5. Other ? <u>see below</u>		✓	

Comments: Other meds: Synthroid 0.112 1x day hypothyroidismBased on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jamie Basemeyer</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-279

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>S/L/B</u> f m l	<u>108</u> Permanent #: <u>11</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one ...			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1997</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: JNB 07/15/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>108</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>S/L/B</u> F M L	Permanent #: <u>11</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Susan L. Harris

Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>S/L/B</u> F. M L	<u>108</u> Permanent #: <u>11</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>145</u>	<u>20</u>	TNTC	<u>180</u>	<u>26</u>
TNTC	<u>155</u>	<u>12</u>	TNTC	<u>194</u>	<u>21</u>
CFU/mL <u>1.5 × 10⁷</u> Counted by: <u>JNB 107-25-03</u>			CFU/mL <u>2.1 × 10⁷</u> Counted by: <u>JNB 107-25-03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>152</u>	<u>17</u>	TNTC	TNTC	<u>150</u>	<u>28</u>		
TNTC	TNTC	<u>179</u>	<u>21</u>	TNTC	TNTC	<u>277</u>	<u>24</u>		
TNTC				TNTC					
CFU/mL <u>1.6 × 10⁵</u> Counted by: <u>JNB 107-25-03</u>				CFU/mL <u>2.4 × 10⁵</u> Counted by: <u>JNB 107-25-03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>124</u>	<u>18</u>	TNTC	TNTC	<u>132</u>	<u>14</u>		
TNTC	TNTC	<u>154</u>	<u>15</u>	TNTC	TNTC	<u>127</u>	<u>15</u>		
TNTC				TNTC					
CFU/mL <u>1.4 × 10⁵</u> Counted by: <u>Qn 107-25-03</u>				CFU/mL <u>1.3 × 10⁵</u> Counted by: <u>Qn 107-25-03</u>					

Calculations by: TU 107-26-03 Raw data reviewed by: Qn 108-1-03Calculations Verified by: JNB 107-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Ⓢ Did not estimate due to countability of the plate. JNB 07-25-03

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-281

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>S / L / B</u> F M L	<u>108</u> Permanent #: <u>//</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/28/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES☒ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:

G. Linn Jones, M.D.

Date

7/28/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>48</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>E L G</u> F M L	Permanent #: <u>12</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>25</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: <u>asthma</u>		✓	

Is the subject taking any medication? If yes, please specify below: dizziness

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ? <u>Singulair 10mg 1xday (asthma)</u>		✓	

Comments: ^{SEP 7/15/03} ^{phen} Phenagran 25mg 1xday (dizziness)
Tylenol 500mg 1xday (headaches)
Ortho - Tri-Cyclen (birth control)
SEP 7/15/03

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.Interviewer's Signature: Stacey E BacklundDate: 07/15/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: **IV - 283**

Visit Code	Date	Subject Initials	Subject Screen #: 148	Study #
Subject Qualification	07/15/03 mm dd yy	E.L.G f m l	Permanent #: 12	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>	<input type="checkbox"/>		1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>		11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one				Subject:
YES	NO	N/A		
	<input checked="" type="checkbox"/>			1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>			2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>			3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>			4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>			6. Has eczema or psoriasis on their hands or wrists ?
Female	<input checked="" type="checkbox"/>	Male		7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <input checked="" type="checkbox"/> Post-menopausal, year If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive 7/24/03 gln
	<input checked="" type="checkbox"/>			8. Is currently lactating ?
	<input checked="" type="checkbox"/>			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>			10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>			12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: **SEB, 7/15/03**

Investigator's Signature: Ann R. Brady	Date: 08/10/03 mm dd yy
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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>148</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>E / L / G</u> F M L	Permanent #: <u>12</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Erin R. Harris

Date: 07 / 24 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>E/L/G</u> F M L	<u>148</u> Permanent #: <u>12</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>141</u>	<u>13</u>	TNTC	<u>134</u>	<u>13</u>
TNTC	<u>132</u>	<u>16</u>	TNTC	<u>135</u>	<u>13</u>
CFU/mL <u>1.4 × 10⁷</u> Counted by: <u>JNB / 07-28-03</u>			CFU/mL <u>1.3 × 10⁷</u> Counted by: <u>JNB / 07-28-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	TNTC	<u>66</u>	<u>10</u>	TNTC	TNTC	<u>111</u>	<u>11</u>
TNTC	TNTC	<u>92</u>	<u>11</u>	TNTC	TNTC	<u>106</u>	<u>11</u>
TNTC				TNTC			
CFU/mL <u>7.8 × 10⁴</u> Counted by: <u>JNB / 07-28-03</u>				CFU/mL <u>1.1 × 10⁵</u> Counted by: <u>JNB / 07-28-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴
TNTC	<u>75</u>	<u>7</u>	<u>1</u>	TNTC	<u>80</u>	<u>10</u>	<u>3</u>
TNTC	<u>98</u>	<u>14</u>	<u>0</u>	TNTC	<u>96</u>	<u>16</u>	<u>1</u>
TNTC				TNTC			
CFU/mL <u>8.6 × 10³</u> Counted by: <u>JNB / 07-28-03</u>				CFU/mL <u>8.8 × 10³</u> Counted by: <u>JNB / 07-28-03</u>			

Calculations by: JNB / 07-29-03 Raw data reviewed by: Alb / 8-1-03Calculations Verified by: TC / 7-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8 / 11 / 03</u> mm dd yy
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Data Collection Form 5A

Subject Initials ELG Subject # 12Study No. 03-122085-106Page No. IV-286

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps	7/25/03	8/11/03	N	1			4	<i>C. J. O'Neil</i> 8-10-03
Entry Date	Comment/Note: Probably due to test organism							Initials
7/28/03	red bumps on right and left hand.							gn
8/11/03	Hand cleans used Cortisone 10 and neosporine 2 times on 7/28/03 and 8/1/03							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
see above for dates	8/11/03							
Entry Date	Comment/Note:							Initials
7-29-03	Three red papules on backs of hands.							C. J. O

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							Initials

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-287

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>E/L/G</u> F M L	<u>148</u> Permanent #: <u>12</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/29/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p><u>3 red papules on backs of hands</u> <u>Onset 7-25-03</u></p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. Lynn Jones, M.D.</u>	Date <u>7/29/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 147	Study #
Subject Qualification	07/15/03 mm dd yy	R/E/P F M L	Permanent #: 13	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>42</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07/15/03</u> mm dd yy
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Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV-289

Visit Code	Date	Subject Initials	Subject Screen #: <u>147</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>R/E/P</u> f m l	Permanent #: <u>13</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SLH / 7-15-03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>147</u>	Study #
Test Period	<u>07/24/03</u> mm dd yy	<u>R/E/P</u> F M L	Permanent #: <u>13</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: <u>Sam R. Harris</u>	Date: <u>07/24/03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 291

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/24/03</u> mm dd yy	<u>R/E/P</u> F M L	<u>147</u> Permanent #: <u>13</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>191</u>	<u>24</u>	TNTC	<u>142</u>	<u>11</u>
TNTC	<u>119</u>	<u>23</u>	TNTC	<u>122</u>	<u>16</u>
CFU/mL <u>1.6×10^7</u> Counted by: <u>JNB 107-28-03</u>			CFU/mL <u>1.3×10^7</u> Counted by: <u>JNB 107-28-03</u>		

LEFT HAND				WASH 1		RIGHT HAND	
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	TNTC	<u>127</u>	<u>24</u>	TNTC	TNTC	<u>199</u>	<u>16</u>
TNTC	TNTC	<u>229</u>	<u>18</u>	TNTC	TNTC	<u>148</u>	<u>19</u>
TNTC				TNTC			
CFU/mL <u>1.8×10^5</u> Counted by: <u>JNB 107-28-03</u>				CFU/mL <u>1.7×10^5</u> Counted by: <u>JNB 107-28-03</u>			

LEFT HAND				WASH 11		RIGHT HAND	
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}
TNTC	<u>100</u>	<u>16</u>	<u>2</u>	TNTC	<u>109</u>	<u>21</u>	<u>2</u>
TNTC	<u>107</u>	<u>14</u>	<u>0</u>	TNTC	<u>126</u>	<u>16</u>	<u>0</u>
TNTC				TNTC			
CFU/mL <u>1.0×10^4</u> Counted by: <u>JNB 107-28-03</u>				CFU/mL <u>1.2×10^4</u> Counted by: <u>JNB 107-28-03</u>			

Calculations by: JNB 107-29-03 Raw data reviewed by AKB 18.1.03Calculations Verified by: TU 17-29-03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>18/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-292

Visit Code	Date	Subject Initials	Subject Screen #: 147	Study #
Follow-up Visit	<u>07/29/03</u> mm dd yy	<u>R/E/P</u> F M L	Permanent #: 13	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

08/01/03 ~~07/29/03~~

mm dd yy

8/1/03

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES☒ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:

E. Linn Jones, MD

Date

8/1/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			208	
Subject Qualification	07/21/03 mm dd yy	P/L/B F M L	Permanent #: 14	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>59</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease? hbp		✓	
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify: HRT, anxiety		✓	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ? Norvasc 10mg 1xday		✓	
4. Insulin ?	✓		
5. Other ? Evista 60 ^{mg} 1xday (HRT)		✓	

Comments:

Potassium 10mg¹⁰ 1xday
 Water Pill 25mg¹⁰ 1xday
 Wellbutrin 150mg¹⁰ 1xday (Anti-depressant)
 Zoloff 50¹⁰ mg 1/2 tablet a c (Anxiety)

⑩ mg added as per subject 7/22/03 ght

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature:

Jarey E. Bachard

Date: 07/21/03
mm dd yy

**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV - 294

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>P/L/B</u> f m l	<u>208</u> Permanent #: <u>14</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/> Surgically Sterile, year <u>1986</u> <input checked="" type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____ Interviewer's Initials/Date: SOB , 7/21/03

Investigator's Signature: _____

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>208</u>	Study #
Test Period	<u>07/29/03</u> mm dd yy	<u>P, L, B</u> F M L	Permanent #: <u>14</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: Stacy E. Barcherdig Date: 07/29/03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>P/L/B</u> F M L	<u>208</u> Permanent #: <u>14</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
<u>TNTC</u>	<u>250</u>	<u>31</u>	<u>TNTC</u>	<u>247</u>	<u>22</u>
<u>TNTC</u>	<u>213</u>	<u>23</u>	<u>TNTC</u>	<u>235</u>	<u>32</u>
CFU/mL <u>2.5 × 10⁷</u> Counted by: <u>TG</u> 17-31-03			CFU/mL <u>2.7 × 10⁷</u> Counted by: <u>TG</u> 17-31-03		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
<u>TNTC</u>	<u>TNTC</u>	<u>98</u>	<u>11</u>	<u>TNTC</u>	<u>TNTC</u>	<u>136</u>	<u>14</u>		
<u>TNTC</u>	<u>TNTC</u>	<u>100</u>	<u>12</u>	<u>TNTC</u>	<u>TNTC</u>	<u>131</u>	<u>11</u>		
<u>TNTC</u>				<u>TNTC</u>					
CFU/mL <u>9.9 × 10⁴</u> Counted by: <u>TG</u> 17-31-03				CFU/mL <u>1.3 × 10⁵</u> Counted by: <u>TG</u> 17-31-03					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
<u>TNTC</u>	<u>88</u>	<u>⊙ LA</u>	<u>2</u>	<u>TNTC</u>	<u>149</u>	<u>19</u>	<u>3</u>		
<u>TNTC</u>	<u>135</u>	<u>15</u>	<u>1</u>	<u>TNTC</u>	<u>157</u>	<u>20</u>	<u>2</u>		
<u>TNTC</u>				<u>TNTC</u>					
CFU/mL <u>1.1 × 10⁴</u> Counted by: <u>SAS</u> 17-31-03				CFU/mL <u>1.5 × 10⁵</u> Counted by: <u>SAS</u> 17-31-03					

⊙ LA=Lab Accident, probable spreading error. SAS 7-31-03

Calculations by: JNB 108-01-03 Raw data reviewed by: SLH 18-6-03Calculations Verified by: SAS 18-1-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-297

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>P, L, B</u> F M L	<u>208</u> Permanent #: <u>14</u>	03-122085-106

Date Subject Entered the Study:

07/21/03

mm dd yy

Follow-Up Visit Date:

08/04/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES ☒ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

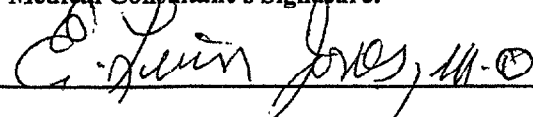
Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES ☒ NO If yes, complete below

Comments:

Medical Consultant's Signature:



Date

8/4/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>24</u>	
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C/R/J</u> F M L	Permanent #: <u>15</u>	03-122085-106

Gender: <input checked="" type="checkbox"/> Male <input type="checkbox"/> Female	Age: <u>37</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease? <u>hbp</u>		✓	
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify: <u>Cholesterol</u>		✓	

Is the subject taking any medication? If yes, please specify below:

back pain

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ? <u>Ibuprofen 80mg 1xday, water pill 25mg 1xday</u>		✓	
4. Insulin ?	/		
5. Other ? <u>Lipitor 10mg 1xday (cholesterol)</u>		✓	

Comments:

Oxycodone 40mg 2xday (back pain)
05/21/03

Based on the above medical history, the subject is:

☒ Qualifiedor ☐

Not qualified for the study.

Interviewer's Signature:

Jacey E. Beckwith

Date:

07/21/03
mm dd yy

Data Collection Form 2
INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: IV - 299

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>211</u>	
Subject Qualification	<u>07/21/03</u> mm dd yy	<u>C, R, J</u> f m l	Permanent #: <u>15</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input type="checkbox"/> Post-menopausal, year _____ If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEB , 7/21/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	07/29/03	C, R, J	211	
Test Period	mm dd yy	F M L	Permanent #:	03-122085-106
			15	

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Stacey E Bachusky Date: 07 / 29 / 03
mm dd yy

Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 301

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/29/03</u> mm dd yy	<u>C/R/J</u> F M L	<u>211</u> Permanent #: <u>15</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>231</u>	<u>18</u>	TNTC	<u>250</u>	<u>30</u>
TNTC	<u>273</u> *	<u>26</u>	TNTC	<u>168</u>	<u>18</u>
CFU/mL <u>2.4 × 10⁷</u> Counted by: <u>TG</u> 17-31-03			CFU/mL <u>2.2 × 10⁷</u> Counted by: <u>TG</u> 17-31-03		

* Not estimated due to countability of the plate. TG 7-31-03

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	TNTC	<u>63</u>	TNTC	TNTC	<u>227</u>	<u>31</u>		
TNTC	TNTC	TNTC	<u>35</u>	TNTC	TNTC	<u>216</u>	<u>16</u>		
TNTC				TNTC					
CFU/mL <u>4.9 × 10⁵</u> Counted by: <u>TG</u> 17-31-03				CFU/mL <u>2.3 × 10⁵</u> Counted by: <u>TG</u> 17-31-03					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>39</u>	<u>3</u>	TNTC	TNTC	<u>54</u>	<u>4</u>		
TNTC	TNTC	<u>37</u>	<u>5</u>	TNTC	TNTC	<u>29</u>	<u>3</u>		
TNTC				TNTC					
CFU/mL <u>3.8 × 10⁴</u> Counted by: <u>SAS</u> 17-31-03				CFU/mL <u>4.2 × 10⁴</u> Counted by: <u>SAS</u> 17-31-03					

Calculations by: JNB 108-01-03 Raw data reviewed by: SLH 18-6-03Calculations Verified by: SAS 18-1-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>Ann R. Brady</u>	Date: <u>08/10/03</u> mm dd yy
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Data Collection Form 5A

Subject Initials C.R.N. Subject # 15Study No. 03-122085-106Page No. IV-302

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Macules	7-30-03	8/3/03	N	1	4(1)	1	4(2)	C. R. N. 8-21-03
Entry Date	Comment/Note: (1) Used Non-Rx cortisone (2) Due to test organism							
8-4-03	Four red macules on the back of the hands							
8/3/03	Hands clear - used cortisone .05 mg 1 time on 7/31/03							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild 2=Moderate 3=Severe

Relationship: 1=Definite 2=Probable 3=Possible 4=Unrelated

Action Taken: 1=None 2=Rx Therapy 3=Discontinued Study 4=Other (specify)

Outcome: 1=Resolved w/o sequelae 2=Resolved w/ sequelae (describe) 3=Ongoing 4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-303

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>211</u>	
Follow-up Visit	<u>08/04/03</u> mm dd yy	<u>C/R/J</u> F M L	Permanent #: <u>15</u>	03-122085-106

Date Subject Entered the Study: <u>07/21/03</u> mm dd yy	Follow-Up Visit Date: <u>08/04/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p><u>Four red macules on backs of hands</u></p> <p><u>Onset 7-30-03</u></p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>C. Levin Jones, MD</u>	Date <u>8/4/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			117	
Subject Qualification	07/15/03 mm dd yy	L1-S F M L	Permanent #: 16	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>60</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	✓		
2. Eczema ?	✓		
3. Skin Cancer ?	✓		
4. Skin Allergies ? Please specify:	✓		
5. Hives ?	✓		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies ? Please specify.	✓		
2. Hepatitis ?	✓		
3. Heart and Vascular Disease?	✓		
4. Liver Disease ?	✓		
5. Kidney Disease ?	✓		
6. Tuberculosis ?	✓		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	✓		
8. Cancer ?	✓		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	✓		
10. Organ transplant ?	✓		
11. Any other condition not listed ? Please specify:	✓		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	✓		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	✓		
3. Heart Medication ?	✓		
4. Insulin ?	✓		
5. Other ?	✓		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Busmer</u>	Date: <u>07 / 15 / 03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: IV-305

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	<u>07/15/03</u> mm dd yy	<u>L-15</u> f m l	<u>117</u> Permanent #: <u>16</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year _____ <input checked="" type="checkbox"/> Post-menopausal, year <u>1990</u> If of child bearing potential - β -HCG Test Results: <input type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 07/15/03

Investigator's Signature: _____

Ann L. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>117</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>L / - / S</u> F M L	Permanent #: <u>16</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: <u>Susan R. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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Data Collection Form 4

HTR Study No.: 03-122085-106

Page No.: IV - 307

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>L-S</u> F. M L	<u>117</u> Permanent #: <u>16</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>151</u>	<u>18</u>	TNTC	<u>209</u>	<u>25</u>
TNTC	<u>194</u>	<u>25</u>	TNTC	<u>220</u>	<u>18</u>
CFU/mL <u>1.9 x 10⁷</u> Counted by: <u>JNB 107-25-03</u>			CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>JNB 107-25-03</u>		

LEFT HAND				WASH 1	RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	
TNTC	TNTC	<u>159</u>	<u>14</u>	TNTC	TNTC	<u>121</u>	<u>29</u>	
TNTC	TNTC	<u>201</u>	<u>20</u>	TNTC	TNTC	<u>172</u>	<u>24</u>	
TNTC				TNTC				
CFU/mL <u>1.8 x 10⁵</u> Counted by: <u>JNB 107-25-03</u>				CFU/mL <u>2.0 x 10⁵</u> Counted by: <u>JNB 107-25-03</u>				

LEFT HAND				WASH 11	RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	
TNTC	TNTC	<u>77</u>	<u>5</u>	TNTC	TNTC	<u>90</u>	<u>12</u>	
TNTC	TNTC	<u>75</u>	<u>6</u>	TNTC	TNTC	<u>59</u>	<u>4</u>	
TNTC				TNTC				
CFU/mL <u>7.6 x 10⁴</u> Counted by: <u>SEP 17/25/03</u>				CFU/mL <u>7.4 x 10⁴</u> Counted by: <u>SEP 17/25/03</u>				

Calculations by: TL 17-26-03 Raw data reviewed by: QNB 18-1-03Calculations Verified by: JNB 107-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-308

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>L - S</u> F M L	<u>117</u> Permanent #: <u>16</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/28/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES☒ NO

If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

Comments:

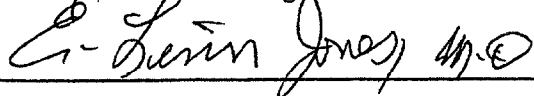
Has the subject had any health related issues since the treatment procedure?

☐ YES☒ NO

If yes, complete below

Comments:

Medical Consultant's Signature:



Date

7/28/03
mm dd yy

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
			<u>125</u>	
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K, L, D</u> F M L	Permanent #: <u>17</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>18</u> Years
--	----------------------

Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify:	<input checked="" type="checkbox"/>		

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ?	<input checked="" type="checkbox"/>		

Comments:

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Jami Busmeyer</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106

Page No.: IV-310

Visit Code	Date	Subject Initials	Subject Screen #: <u>125</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>K/L/D</u> f m l	Permanent #: <u>17</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u> </u> <input type="checkbox"/> Post-menopausal, year <u> </u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive <u>7/23/03</u>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: JNB 07.15.03

Investigator's Signature: _____

Ann P. Budy

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>125</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>K/L/D</u> F M L	Permanent #: <u>17</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician
☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments:

Interviewer's Signature: <u>Sam L. Harris</u>	Date: <u>07 / 23 / 03</u> mm dd yy
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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>K/L/D</u> F. M L	<u>125</u> Permanent #: <u>17</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>180</u>	<u>6</u>	TNTC	<u>177</u>	<u>6</u>
TNTC	<u>188</u>	<u>12</u>	TNTC	<u>138</u>	<u>14</u>
CFU/mL <u>1.8 x 10⁷</u> Counted by: <u>SEP 17/25/03</u>			CFU/mL <u>1.6 x 10⁷</u> Counted by: <u>SEP 17/25/03</u>		

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>72</u>	<u>5</u>	TNTC	TNTC	<u>42</u>	<u>8</u>		
TNTC	TNTC	<u>53</u>	<u>7</u>	TNTC	TNTC	<u>58</u>	<u>8</u>		
TNTC				TNTC					
CFU/mL <u>6.2 x 10⁴</u> Counted by: <u>SEP 17/25/03</u>				CFU/mL <u>5.2 x 10⁴</u> Counted by: <u>SEP 17/25/03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>89</u>	<u>8</u>	TNTC	TNTC	<u>160</u>	<u>17</u>		
TNTC	TNTC	<u>87</u>	<u>14</u>	TNTC	TNTC	<u>137</u>	<u>18</u>		
TNTC				TNTC					
CFU/mL <u>8.8 x 10⁴</u> Counted by: <u>SEP 17/25/03</u>				CFU/mL <u>1.5 x 10⁵</u> Counted by: <u>SEP 17/25/03</u>					

Calculations by: TL 17-26-03 Raw data reviewed by ALB 18-1-03Calculations Verified by: JNB 107-29-03*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count


Investigator's Signature: <u>[Signature]</u>	Date: <u>8/11/03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-313

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>K/L/D</u> F M L	<u>125</u> Permanent #: <u>17</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: 	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>V/L/W</u> F M L	<u>136</u> Permanent #: <u>18</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>44</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	<input checked="" type="checkbox"/>		
2. Eczema ?	<input checked="" type="checkbox"/>		
3. Skin Cancer ?	<input checked="" type="checkbox"/>		
4. Skin Allergies ? Please specify:	<input checked="" type="checkbox"/>		
5. Hives ?	<input checked="" type="checkbox"/>		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	<input checked="" type="checkbox"/>		
2. Hepatitis ?	<input checked="" type="checkbox"/>		
3. Heart and Vascular Disease?	<input checked="" type="checkbox"/>		
4. Liver Disease ?	<input checked="" type="checkbox"/>		
5. Kidney Disease ?	<input checked="" type="checkbox"/>		
6. Tuberculosis ?	<input checked="" type="checkbox"/>		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	<input checked="" type="checkbox"/>		
8. Cancer ?	<input checked="" type="checkbox"/>		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	<input checked="" type="checkbox"/>		
10. Organ transplant ?	<input checked="" type="checkbox"/>		
11. Any other condition not listed ? Please specify: <u>underactive thyroid, migraines, acid reflux, hiatal hernia</u>		<input checked="" type="checkbox"/>	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	<input checked="" type="checkbox"/>		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	<input checked="" type="checkbox"/>		
3. Heart Medication ?	<input checked="" type="checkbox"/>		
4. Insulin ?	<input checked="" type="checkbox"/>		
5. Other ? <u>Synthroid 0.112 mg 1x day (thyroid)</u>		<input checked="" type="checkbox"/>	

Comments: Propranolol 40mg 2x day (migraines)
Celebra 40mg 1x day (anti-depressant, & migraines)
Wellbutrin 150mg 1x day (anti-depressant)
Prevacid 30^{mg} 1x day (acid reflux)
@ added as per subject 7/16/03 gh

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Stacey E. Beckending</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: **IX-315**

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>V, L, W</u> f m l	<u>136</u> Permanent #: <u>18</u>	03-122085-106

INCLUSION CRITERIA

Check one		Subject:
YES	NO	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has signed informed consent ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Is currently participating in another clinical study at this or any other facility ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Has participated in any type of hand or arm wash study within the past 7 days ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Has artificial nails or nail tips ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Has eczema or psoriasis on their hands or wrists ?
Female	Female	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u>7/23/03</u> <input type="checkbox"/> Post-menopausal, year <u>7/23/03</u> If of child bearing potential - β-HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Is currently lactating ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SEP, 7/15/03

Investigator's Signature: _____

Ann R. Bruf

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>136</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>V / L / W</u> F M L	Permanent #: <u>18</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No
If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No
If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Betty M. Conover

Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>V/L/W</u> F M L	<u>136</u> Permanent #: <u>18</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10^{-4}	10^{-5}	10^{-6}	10^{-4}	10^{-5}	10^{-6}
TNTC	<u>115</u>	<u>16</u>	TNTC	<u>145</u>	<u>14</u>
TNTC	<u>127</u>	<u>14</u>	TNTC	<u>134</u>	<u>12</u>
CFU/mL <u>1.8×10^7</u> Counted by: <u>JNB</u> /07.25.03			CFU/mL <u>1.4×10^7</u> Counted by: <u>JNB</u> /07.25.03		

② TG 7.29.03

LEFT HAND				WASH 1		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
TNTC	TNTC	TNTC	<u>42</u>	TNTC	TNTC	<u>150</u>	<u>22</u>		
TNTC	TNTC	TNTC	<u>42</u>	TNTC	TNTC	<u>165</u>	<u>23</u>		
TNTC				TNTC					
CFU/mL <u>4.2×10^5</u> Counted by: <u>JNB</u> /07.25.03				CFU/mL <u>1.6×10^5</u> Counted by: <u>JNB</u> /07.25.03					

LEFT HAND				WASH 11		RIGHT HAND			
10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-1}	10^{-2}	10^{-3}	10^{-4}		
TNTC	TNTC	<u>176</u>	<u>19</u>	TNTC	TNTC	<u>177</u>	<u>21</u>		
TNTC	TNTC	<u>177</u>	<u>20</u>	TNR	TNTC	<u>144</u>	<u>19</u>		
TNTC				TNTC					
CFU/mL <u>1.8×10^5</u> Counted by: <u>gn</u> /7.25.03				CFU/mL <u>1.6×10^5</u> Counted by: <u>gn</u> /7.25.03					

Calculations by: TG /7.26.03 Raw data reviewed by AOB /8.1.03Calculations Verified by: JNB /07.29.03* 10^{-1} dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: La MallyDate: 8/11/03
mm dd yy

Data Collection Form 5A

Subject Initials VLW Subject # 18Study No. 03-122085-106Page No. IV-318

ADVERSE EVENTS

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
red bumps	7/24/03	7/14/03	N	1	4(1)	1	4(2)	<i>[Signature]</i> 8-21-03
Entry Date	Comment/Note: (1) Used Non-Rx. Neosporin (2) Duct to test organism							
7/25/03	red bumps on both hands and wrists							
	right seven bumps, left 3 bumps							
7/14/03	Hands + wrists clear - neosporin							
	used at night from 7/24/03 - 8/13/03							
	as needed.							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigator Signature/Date
Entry Date	Comment/Note:							

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity: 1=Mild

2=Moderate

3=Severe

Relationship: 1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken: 1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome: 1=Resolved w/o sequelae

2=Resolved w/ sequelae (describe)

3=Ongoing

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

Page No.: IV-319

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>V / L / W</u> F M L	<u>136</u> Permanent #: <u>18</u>	03-122085-106

Date Subject Entered the Study: <u>07/15/03</u> mm dd yy	Follow-Up Visit Date: <u>07/28/03</u> mm dd yy
<p>Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?</p> <p><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO If yes, complete below:</p> <p>Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)</p> <p><u>Six red papules on hands and wrists</u></p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>Has the subject had any health related issues since the treatment procedure?</p> <p><input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If yes, complete below</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p>	

Medical Consultant's Signature: <u>E. Linn Jones, M.D.</u>	Date <u>7/28/03</u> mm dd yy
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Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>128</u>	Study #
Subject Qualification	<u>07/15/03</u> mm dd yy	<u>D/L/S</u> F M L	Permanent #: <u>19</u>	03-122085-106

Gender: <input type="checkbox"/> Male <input checked="" type="checkbox"/> Female	Age: <u>43</u> Years
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Does the subject have any of the following at the treatment sites?

I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	/		
2. Eczema ?	/		
3. Skin Cancer ?	/		
4. Skin Allergies ? Please specify:	/		
5. Hives ?	/		

Does the Subject have any of the following (present and past)?

II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies? Please specify.	/		
2. Hepatitis ?	/		
3. Heart and Vascular Disease?	/		
4. Liver Disease ?	/		
5. Kidney Disease ?	/		
6. Tuberculosis ?	/		
7. Diabetes ? Controlled? Diet [] Oral [] Insulin []	/		
8. Cancer ?	/		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.) ?	/		
10. Organ transplant ?	/		
11. Any other condition not listed ? Please specify: <u>back pain, depression, sinus</u>		/	

Is the subject taking any medication? If yes, please specify below:

III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic ?	/		
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs ?	/		
3. Heart Medication ?	/		
4. Insulin ?	/		
5. Other ? <u>Paxil 50mg CR taken 1x/day (depression)</u>		/	

Comments: (back pain) Darvocet 100mg taken as needed, Robaxin 750mg taken as needed (back pain)
Ambien 0.25mg taken as needed (sleep)
Adorax 25mg taken as needed (sinus)
XZANAX 0.25mg taken as needed (nerves)
SEP 7/15/03 Feuricet 750mg taken when needed (tension headaches)

Based on the above medical history, the subject is: ☒ Qualified or ☐ Not qualified for the study.

Interviewer's Signature: <u>Stacy E Bocheiding</u>	Date: <u>07/15/03</u> mm dd yy
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**Data Collection Form 2
INCLUSION / EXCLUSION FORM**

HTR Study No.: 03-122085-106
Page No.: **IV - 321**

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Subject Qualification	<u>67/15/03</u> mm dd yy	<u>D/L/S</u> f m l	<u>128</u> Permanent #: <u>19</u>	03-122085-106

INCLUSION CRITERIA

Check one			Subject:
YES	NO		
<input checked="" type="checkbox"/>			1. Is 18 through 65 years ?
<input checked="" type="checkbox"/>			2. Has signed informed consent ?
<input checked="" type="checkbox"/>			3. Is healthy as evidenced by responses on DCF 1 ?
<input checked="" type="checkbox"/>			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?
<input checked="" type="checkbox"/>			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed ?
<input checked="" type="checkbox"/>			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study ?
<input checked="" type="checkbox"/>			7. Is willing to refrain from using anti-dandruff shampoo during the entire study ?
<input checked="" type="checkbox"/>			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness ?
<input checked="" type="checkbox"/>			11. Is willing to comply with all study protocol requirements ?

EXCLUSION CRITERIA

Check one			Subject:
YES	NO	N/A	
	<input checked="" type="checkbox"/>		1. Is currently participating in another clinical study at this or any other facility ?
	<input checked="" type="checkbox"/>		2. Has participated in any type of hand or arm wash study within the past 7 days ?
	<input checked="" type="checkbox"/>		3. Has cuts, lesions, or other skin disorders on their hands or wrists ?
	<input checked="" type="checkbox"/>		4. Has artificial nails or nail tips ?
	<input checked="" type="checkbox"/>		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies ?
	<input checked="" type="checkbox"/>		6. Has eczema or psoriasis on their hands or wrists ?
Female	<input checked="" type="checkbox"/>	Male	7. Is currently pregnant ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Of child-bearing potential: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Surgically Sterile, year <u>7/23/03</u> <input type="checkbox"/> Post-menopausal, year <u>98</u> If of child bearing potential - β -HCG Test Results: <input checked="" type="checkbox"/> negative <input type="checkbox"/> positive
	<input checked="" type="checkbox"/>		8. Is currently lactating ?
	<input checked="" type="checkbox"/>		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis ?
	<input checked="" type="checkbox"/>		10. Has another medical condition which in the opinion of the Investigator would preclude participation ?
	<input checked="" type="checkbox"/>		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	<input checked="" type="checkbox"/>		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps ?

Based upon dermatologic evaluation and the information contained in Data Collection Forms 1 and 2, the subject is:
☒ **Qualified** ☐ **Not Qualified** for participation in this study.

Reasons for disqualification: _____

Interviewer's Initials/Date: SB , 7/15/03

Investigator's Signature: _____

Ann R. Brady

Date: 08/10/03
mm dd yy

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #: <u>128</u>	Study #
Test Period	<u>07/23/03</u> mm dd yy	<u>2 / L / S</u> F M L	Permanent #: <u>19</u>	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? ☒ Yes ☐ No

If no, please indicate condition: _____

II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? ☒ Yes ☐ No

If no, please explain: _____

III. Has subject been ill since the last visit? ☐ Yes (Complete below) ☒ No

IV. Has subject used any new oral or topical medication? ☐ Yes (Complete below) ☒ No

Based upon the above responses, the subject is: ☒ Qualified ☐ Not Qualified to continue on the study.

Reasons for disqualification: _____

TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS

Date of Onset: _____ Date Reported: _____ Date Resolved: _____

Describe condition: _____

Was reaction related to treatment? ☐ Not related ☐ Possibly related ☐ Definitely related ☐ Other (explain)

Action Taken: ☐ None ☐ Continued on study ☐ Withdrawn from the study ☐ Consulted physician

☐ Medication taken (Complete below) ☐ Hospitalized ☐ Other (explain)

Additional Comments: _____

CONCOMITANT MEDICATION

Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		/ /	/ /	
		/ /	/ /	
		/ /	/ /	

Comments: _____

Interviewer's Signature: Betty M. Conover

Date: 07 / 23 / 03
mm dd yy

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study #
<u>07/23/03</u> mm dd yy	<u>D/L/S</u> F M L	<u>128</u> Permanent #: <u>19</u>	03-122085-106

BASELINE					
LEFT HAND DILUTIONS			RIGHT HAND DILUTIONS		
10 ⁻⁴	10 ⁻⁵	10 ⁻⁶	10 ⁻⁴	10 ⁻⁵	10 ⁻⁶
TNTC	<u>140</u>	<u>24</u>	TNTC	<u>220</u>	<u>21</u>
TNTC	<u>10 261</u>	<u>25</u>	TNTC	<u>159</u>	<u>25</u>
CFU/mL <u>2.2 x 10⁷</u> Counted by: <u>SEP 7/25/03</u>			CFU/mL <u>2.1 x 10⁷</u> Counted by: <u>SEP 7/25/03</u>		

① Did not estimate due to plate countability. SEP 7/25/03

LEFT HAND				WASH 1		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>114</u>	<u>13</u>	TNTC	TNTC	TNTC	<u>40</u>		
TNTC	TNTC	<u>78</u>	<u>11</u>	TNTC	TNTC	TNTC	<u>40</u>		
TNTC				TNTC					
CFU/mL <u>9.6 x 10⁴</u> Counted by: <u>SEP 7/25/03</u>				CFU/mL <u>4.0 x 10⁵</u> Counted by: <u>SEP 7/25/03</u>					

LEFT HAND				WASH 11		RIGHT HAND			
10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴		
TNTC	TNTC	<u>109</u>	<u>7</u>	TNTC	TNTC	<u>188</u>	<u>19</u>		
TNTC	TNTC	<u>118</u>	<u>7</u>	TNTC	TNTC	<u>154</u>	<u>20</u>		
TNTC				TNTC					
CFU/mL <u>1.1 x 10⁵</u> Counted by: <u>SEP 7/25/03</u>				CFU/mL <u>1.7 x 10⁵</u> Counted by: <u>SEP 7/25/03</u>					

Calculations by: TG 7/26/03 Raw data reviewed by: Q66 10.1.03

Calculations Verified by: JNB 107.29.03

*10⁻¹ dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature: <u>[Signature]</u>	Date: <u>8</u> / <u>11</u> / <u>03</u> mm dd yy
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FOLLOW-UP VISIT

Page No.: IV-324

Visit Code	Date	Subject Initials	Subject Screen #: <u>128</u>	Study #
Follow-up Visit	<u>07/28/03</u> mm dd yy	<u>D/L/S</u> F M L	Permanent #: <u>19</u>	03-122085-106

Date Subject Entered the Study:

07/15/03

mm dd yy

Follow-Up Visit Date:

07/28/03

mm dd yy

Does the subject's hands have the presence of pimples, blisters, or raised itching bumps surrounded by erythema and/or edema that may be indicative of a skin infection?

☐ YES ☒ NO If yes, complete below:

Clinical Observations: (Include date of onset and descriptions/severity/locations, etc.)

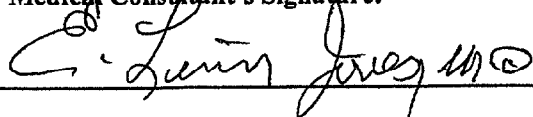
Comments:

Has the subject had any health related issues since the treatment procedure?

☐ YES ☒ NO If yes, complete below

Comments:

Medical Consultant's Signature:



Date

7/28/03
mm dd yy